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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566
23980 7590 08/20/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C 5 Palo Alto Square - 6th Floor 3000 El Camino Real PALO ALTO, CA 94306-2155				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
08/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,103

Applicant(s)

SINGH ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5/ICE)
Paper No(s)/Mail Date 07/24/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 06/05/2009; and IDS filed 07/24/2009.

Claims 1-59 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/05/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 failed to further limit claim 1 because claim 1 as

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amended recites the composition comprises active agent, and claim 39 recites that active agent is present.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Therriault et al. (US 4,904,247) and Inaba et al. (US 4,552,751).

Applicant Claims

Applicants' claim 1 is directed to composition comprising

- (1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer;
- (2) active agent, and
- (3) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Therriault teaches laminate structure wherein each layer comprising composition for topical delivery of active agent comprising plasticized hydrophilic blend of polymers forming hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties (abstract; co1.2, lines 29-38; co1.3, lines 65-68). The reference teaches the

layers comprised of 40- 80% of water soluble polymer selected from homopolymer of N-vinyl lactam or copolymers of N-vinyl lactam including polyvinyl pyrrolidone, 20-60% of water insoluble acrylic or methacrylic polymers, and 20-40% of plasticizer (co1.4, lines 1-41,53-68; co1.5, lines 1-30, 57-63). The plasticizer is polyethylene glycol having MW between 200-800 that disclosed by applicants as the complementary oligomer. Drugs and medicaments can be included into the composition (co1.3, lines 22-24). The claimed amounts of each component overlaps the ranges taught by the reference, and the reference further teaches that properties of the hydrophilic blend such pressure sensitive property or non-tacky property is determined by the proportions of the hydrophilic polymer and plasticizer (co1.5, lines 10-20). Therefore, one having ordinary skill in the art would have been motivated to adjust the amount of individual polymers in order to achieve the desired properties of adhesiveness, absorbency, etc., according to the specific intended use.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Therriault teaches multi-laminate of hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties, however, Therriault do not specify that erodible backing layer as claimed by instant claim 1.

Inaba teaches multilayered film preparation that dissolves in body fluid, the film comprises active agent storage layers comprise one or more of: 10-80% water soluble

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polymer, 10-30% plasticizer that reads on the claimed oligomer, and drug. Inaba further teaches drug release controlling layer comprises water soluble and water insoluble polymers, which reads on the erodible backing layer (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51; claim 1). The water soluble polymer comprises hydroxymethyl cellulose, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol, all currently claimed as oligomer (col.2, lines 12-28). The erosion of the layer that controls the release of the active agent and made of water insoluble polymer is expected to be slower than layer containing water soluble polymers. The time of erosion of the multilayered film depends on the percentage of water soluble, water insoluble, and plasticizers. The multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose (abstract, col.1, lines 450-50).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Theriault, and replace one layer of the laminate with a layer that have slower solubility and erosion comprising cellulose derivatives as taught

by Inaba. One would have been motivated to do so because Inaba teaches that multilayered film that has different time of erosion of the different layers provides the desired long lasting release pattern at a required concentration required for therapeutic purpose. One would reasonably expected formulating laminate wherein one layer of the laminate comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises polymer having slower erosion to provide long lasting release pattern of the active agent.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Theriault et al. (US 4,904,247) combined with Tapolsky et al. (5,800,832).

Applicant Claims

Applicants' claim 1 is directed to composition comprising

- (1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer;
- (2) active agent, and
- (3) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Therriault teaches laminate structure wherein each layer comprising composition for topical delivery of active agent comprising plasticized hydrophilic blend of polymers forming hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties (abstract; co1.2, lines 29-38; co1.3, lines 65-68). The reference teaches the layers comprised of 40- 80% of water soluble polymer selected from homopolymer of N-vinyl lactam or copolymers of N-vinyl lactam including polyvinyl pyrrolidone, 20-60% of water insoluble acrylic or methacrylic polymers, and 20-40% of plasticizer (co1.4, lines 1-41,53-68; co1.5, lines 1-30, 57-63). The plasticizer is polyethylene glycol having MW between 200-800 that disclosed by applicants as the complementary oligomer. Drugs and medicaments can be included into the composition (co1.3, lines 22-24). The claimed amounts of each component overlaps the ranges taught by the reference, and the reference further teaches that properties of the hydrophilic blend such pressure sensitive property or non-tacky property is determined by the proportions of the hydrophilic polymer and plasticizer (co1.5, lines 10-20). Therefore, one having ordinary skill in the art would have been motivated to adjust the amount of individual polymers in

order to achieve the desired properties of adhesiveness, absorbency, etc., according to the specific intended use.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Therriault teaches multi-laminate of hydrophilic layers being capable of forming hydrogel and characterized by high absorbency, strength mechanical integrity, comfort, transparency and bacterial barrier properties, however, Therriault do not specify that erodible backing layer as claimed by instant claim 1.

Tapolsky teaches erodible pharmaceutical device for application to the mucosal surface, the device comprising one adhesive layer and backing layer (abstract). Both layers are water soluble, i.e. erodible, and provide effective residence time and minimal discomfort and ease of use (col.3, lines 20-33). The adhesive layer comprises one polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble polymer (col.3, lines 34-39; col.5, lines 37-60; example 11). The backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose or hydroxypropylmethyl cellulose (col.3, lines 40-45). The residence time of the device depends on the dissolution rate of the water soluble polymers, and the dissolution rate may be adjusted by adjusting the mixed amounts of the polymers, therefore the erosion time of the device claimed by claims 29-36 are expected to be obtained by adjusting the ratios of water soluble and water swellable polymers according to specific intended use (col.4,

line 66-col.4, line 5). The film may contain therapeutic agent, flavoring agent and coloring agent (col.7, line6-col.8, line 10).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein each layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer and active agent as taught by Therriault, and replace one layer of the laminate with the erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the device having erodible backing layer provides effective residence time and minimal discomfort and ease of use. One would reasonably expect formulating laminate that is comfortable and easy to use and comprises one layer comprising hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises is erodible cellulose derivative and further adjust dissolution of the backing layer according to specific intended use and site of application.

Regarding the limitation of slower erosion of the backing layer than the hydrogel, Tapolsky teaches dissolution rate may be adjusted by adjusting the mixed amounts of the polymers. Therefore, one having ordinary skill in the art at the time of the invention would have been able to adjust the polymers to obtain the desired dissolution time of the backing layer according to the intended use and site of application.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Claims 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the combination of Therriault and Inaba, or the combination of Therriault and Tapolsky, each combination further in view of Sagel et al. (US 5,891,453).

The combined teachings of Therriault and Inaba and the combination of Therriault and Tapolsky are previously discussed as set forth in this office action.

Although the combinations of the references teach active agent, however, the references do not teach teeth whitening material as claimed by claims 42-49, and teeth whitening method as claimed by claims 50-59.

Sagel teaches strip for teeth whitening comprising gel comprising tooth whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof (abstract, examples; claim 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide laminate wherein one layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent, and a second layer comprises erodible polymer as taught by the combined teaching of Therriault and Inaba or Therriault and Tapolsky, and replace the active agent by teeth whitening agent selected from peroxides and metal chlorites

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as taught by Sagel. One would have been motivated to do so because Sagel teaches that such materials as preferred material for tooth whitening for inclusion in gel strips applied to the mucus membrane. One would reasonably expect formulating laminate wherein one layer comprises hydrophilic composition comprising water swellable water-insoluble polymer, water soluble polymer, oligomer, and active agent selected from peroxide or metal chlorite that whiten teeth, and a second layer comprises polymer having slower erosion, wherein the laminate when applied to teeth will whiten the teeth effectively and safely with great success.

Response to Arguments

10. Applicant's arguments with respect to claims 1-59 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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